

REMARKS

Claims 1-3, 5, 7-9, 11-18 and 20-22 were pending in this application. Claims 1, 2, 11, 12 and 20 have been amended. Claims 7, 9, 13-16, 18 and 21 have been cancelled without prejudice or disclaimer. Claim 23 has been added. No new matter has been added.

ARGUMENTS

Rejection of the Claims (in various combinations) under Section 102(b) as anticipated by Heath and/or White

The Examiner states on page 5 ¶2 of the Office Action that Nitinol is biodegradable, citing White (at Col. 5, lines 9-10) “[...Examples of materials include...]nitinol, particularly biodegradable nitinol”. In response, Applicant respectfully submits that this one mention is insufficient to establish that Nitinol materials are generally biodegradable. Nitinol is substantially non-biodegradable. In support of this proposition, Applicant submits herewith an article entitled “Biocompatibility Studies of the Anaconda Stent-Graft and Observations of Nitinol Corrosion Resistance” (J Endovas Ther 2004; 11:385-403), which indicates (at p. 385) that the Nitinol stents studied showed no signs of corrosion. Applicant further submits herewith a review/discussion of the biocompatibility of Nitinol (“Biocompatibility of Nitinol”, Johnson Matthey Medical, © 2010, <http://jmmedical.com/resources/241/Biocompatibility-of-Nitinol.html>), which also states “The excellent biocompatibility, very high corrosion resistance, and excellent cytocompatibility of Nitinol has made these unique applications possible. The Nickel in Nitinol is chemically joined to the Titanium in a strong intermetallic bond, so the risk of reaction, even in patients with Nickel-sensitivity, is extremely low.” There are many other published articles confirming that Nitinol typically has very low bio-corrodibility/degradability; i.e., degradability sufficiently slow as to be essentially non-degradable for medical (e.g., implant) purposes. Accordingly, Applicant respectfully submits that the Examiner’s argument and the citation of White that Nitinol is biodegradable is factually at odds with the published literature. Furthermore, the statement referred to in White, even taken at face value, is a mere mention and does not disclose examples of such materials.

One of ordinary skill in the art would not be able to ascertain from the quantum of disclosure in White that Nitinol is biodegradable or to be able to identify any particular Nitinol material that could be used or adapted to obtain the presently claimed invention. Accordingly, White does not anticipate the presently claimed invention.

Heath is discussed and distinguished in Applicant's prior response of September 15, 2009, restated here as follows. Regarding the rejections of the claims under Section 102(b) as being anticipated by Heath, the present application as well as Heath describes a composite material. A composite material is a material of two or more connected substances. The properties of these composite materials differ in substance, on the one hand, and, the geometry of the single substances, on the other hand. This can lead to distinct composite materials which differ from each other in fundamental and significant ways. Thus the material of the present application differs considerably from the material disclosed in Heath.

The disclosed materials of Heath describe a so-called laminated composite material. In contrast, the marker according to the presently claimed invention describes a particle composite material, also called a dispersion material. These two materials differ, among other things, in their substantial properties. Heath's laminate composite material is intended to combine the elasticity of one component with the radiopacity of the other component to produce a flexible tube. In contrast, the material of the present claims incorporates a fine dispersion of particles in the marker component to provide opacity as well as bio-inertness upon degradation of the marker.

Heath describes a radio-opaque material utilizable as an implant. This material possesses a core-shell assembly wherein the core consists of Ta. This core structure can serve as a marker but is at no time in direct contact with body tissue. The marker substance is completely encapsulated by the shell. Therefore, no interaction in view of degradation of the material can occur, which is an essential feature of the radio-opaque marker according to the presently claimed invention. The marker according to the presently claimed invention features a structure wherein the marker component is in principle via dispersion in contact with the tissue.

Furthermore, Heath notes that the shell material of the composite material can consist of NiTi, CuZnAl or CuAuZn. These alloys are not biodegradable. In fact, they are characterized as having an excellent corrosion stability which is essential if toxic elements such as, for example, Ni are used in the alloy. Implants of pure Ni would not normally be used in the human body. Only an alloy with Ti, especially in the adequate ratio of mixture, makes sure to use these implants. The same is true for the CuZnAl and CuAuZn alloys. That further elements are added to the alloys may be the result of the optimization of the material properties like elasticity or fragility. However, the alloys described in Heath differ basically from the biodegradable base component according to the presently claimed invention.

Accordingly, the presently claimed invention, which incorporates a biodegradable base component, is not disclosed in Heath. As noted above, White does not teach to one of ordinary skill in the art a sufficient level of detail as to be able, taken with Heath, to anticipate the presently claimed invention.

New Claim 23 further clarifies Claim 1 and the marker component in contact with body material when dispersed. Such material is distinguishable from the laminate composite material of Heath.

Thus, the presently claimed invention is distinguishable over the cited art.

Rejection of Claims 11-15, and 20-22 (in various combinations) under Section 103(a) as unpatentable over Meyer-Lindenberg et al.

Claims 13-16 have been canceled. Meyer-Lindenberg does not disclose teach or suggest the use of fine particles as a radiopaque material used in conjunction with the marker base component as stated in the claims as presently submitted.

CONCLUSION

Applicant submits that the present application is in condition for allowance and respectfully requests such action. If the Examiner has any questions that can be answered by telephone, please contact the undersigned attorney of record at the telephone number listed below. It is requested that, if necessary to effect a timely response, this paper be considered a Petition for an Extension of Time sufficient to effect a timely response with the fee for such extensions and shortages in other fees being charged, or any overpayment in fees being credited, to the Account of Barnes & Thornburg LLP, Deposit Account No. **50-4913**.

Respectfully submitted,
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